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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,638	12/15/2003	Philippe Rouanet	029488-0113	9056

22428 7590 12/11/2007

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,638	ROUANET ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-36,38,39 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-36,38,39 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 11/27/2007 has been fully considered. It is noted that Applicants filed a Rule 132 Declaration.

Response to Arguments

Applicants acknowledge that during the interview of 11/14/2007, the issue was raised that the Declaration did not fully encompass the range of 0.5-2.0% weight of the composition of IPM as claimed. The Declaration gives data showing 0.5%, 0.7% and 0.9% of IPM, but not amounts on the upper end of the recited range (1.1-2.0% by weight). Applicants argue that the compositions comprising IPM in the Declaration demonstrate that IPM is an effective penetration enhancer at concentrations that are lower than those mentioned by Parab (EP 0 513 832 of record) and that there is no indication in the data that compositions comprising up to 2% of IPM would not also demonstrate penetration enhancement.

In response to the above arguments, it is noted on page 5 of the Declaration that Applicants state that "...IPM is an effective penetration enhancer for 4-OHT when used at concentrations below 1.0%....". The data indicate that concentrations below 1.0% are effective. Though the Examiner understands the meaning of the error bars in the figure given on page 5, it is noted that there still appears to be a downward trend at concentrations of IPM at 0.9% and it is unclear if this downward trend would continue at higher concentrations or not. Therefore, the data is not commensurate in scope with the claims.

Applicant's arguments regarding the filing of a Terminal Disclaimer over co-pending application 10/734,640 have been found persuasive in the sense that both applications were filed on the same day. In the case of two applications being filed on the same day, the MPEP states that "If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer. MPEP § 804. Accordingly, the present application is being treated as the base invention because it is drawn to a composition and application 10/734,640 is being treated as the improvement since it is drawn to a method of use. Therefore, the ODP rejection will not be made in this application.

Due to Applicants amendments to the claims, the following modified rejections are being given below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-34, 36, 39, 43-45 and 47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990.

Mauvais-Jarvis et al. teaches a percutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen, and which can also comprise the steroid hormone progesterone (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular). Mauvais-Jarvis et al. further exemplifies a composition comprising progesterone, 4-hydroxytamoxifen, ethyl alcohol and water (see column 3, lines 30-45, in particular). Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular).

Regarding claim 39, it is noted that as Mauvais-Jarvis et al. teaches that the composition can contain the active agent that is 4-hydroxytamoxifen, it is considered that the reference teaches providing a composition in which 4-hydroxytamoxifen is the sole pharmaceutically active agent. Also, the composition containing 4-hydroxytamoxifen and progesterone of Mauvais-Jarvis et al. is considered to meet the limitation of being a composition "comprising a pharmaceutically active agent ... wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen" (underline added, i.e. a composition that has at least one pharmaceutically active agent that is 4-hydroxy tamoxifen) as recited in claim, because the composition contains an active agent that is 4-hydroxy tamoxifen.

It is furthermore noted that Mauvais-Jarvis et al. teaches that the percutaneous administration composition and method arose out of studies with percutaneous administration of hormonal steroids such as progesterone (see column 1, lines 56-column 2, line 25, in particular), and thus teaches that the methods and vehicles suitable for percutaneous administration of hormonal steroids can also be used for the percutaneous administration of the 4-hydroxytamoxifen.

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a fatty acid ester penetration enhancer, such as isopropyl myristate, as recited in claims 31 and 39.

Gunther et al. teaches a composition for transdermal administration of steroid hormones comprising a fatty acid ester (see abstract, in particular). Gunther et al. teaches that fatty acid esters ensure adequate penetration of the active ingredient through the skin for therapy, and that a preferred fatty acid ester is isopropyl myristate (see specification, first page, in particular), as recited in claims 31 and 39.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen and progesterone

steroid composition comprises ingredients to enable percutaneous penetration, and Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen and progesterone composition.

It would furthermore have been obvious to one of ordinary skill in the art at the time the invention was made to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that vehicles suitable for the percutaneous administration of steroidal hormones can also be used for the percutaneous administration of 4-hydroxytamoxifen, whereas Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen.

Accordingly, claims 31 and 39 are obvious over the teachings of Mauvais-Jarvis et al. in view of Gunther et al.

Regarding claims 31 and 39, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water, and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Regarding the amount of the isopropyl myristate provided, as recited in part (b) of claims 31 and 39, as well as claims 33 and 44, it is noted that Gunther et al. exemplifies compositions with 10% and 2% isopropyl myristate. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 32 and 43, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular). Gunther teaches that concentration of active ingredient of from 0.2 to 20 weight percent can be provided by utilizing the fatty acid ester penetration enhancers (see first page, in particular). Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition, according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Gunther, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 34 and 45, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding claims 36 and 47, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found

it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 31-34, 36, 39, 43-45 and 47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992.

Mauvais-Jarvis et al. teaches a percutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen, and which can also comprise the steroid hormone progesterone (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular). Mauvais-Jarvis et al. further exemplifies a composition comprising progesterone, 4-hydroxytamoxifen, ethyl alcohol and water (see column 3, lines 30-45, in particular). Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular).

Regarding claim 39, it is noted that as Mauvais-Jarvis et al. teaches that the composition can contain the active agent that is 4-hydroxytamoxifen, it is considered

that the reference teaches providing a composition in which 4-hydroxytamoxifen is the sole pharmaceutically active agent. Also, the composition containing 4-hydroxytamoxifen and progesterone of Mauvais-Jarvis et al. is considered to meet the limitation of being a composition "comprising a pharmaceutically active agent ... wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen" (underline added, i.e. a composition that has at least one pharmaceutically active agent that is 4-hydroxy tamoxifen) as recited in claim, because the composition contains an active agent that is 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a fatty acid ester penetration enhancer, such as isopropyl myristate, as recited in claims 31 and 39.

Parab teaches enhancing the dermal or transdermal penetration of topically applied pharmacologically active agents (see abstract, in particular). Parab teaches that isopropyl myristate is known as a penetration enhancer for topical preparations (see page 2, lines 57-58, in particular).

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Parab in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen comprises ingredients

to enable percutaneous penetration, and Parab et al. teaches that the isopropyl myristate is a known penetration enhancer that can be used in compositions intended to enhance the penetration of pharmacological active agents. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen.

Regarding claims 28 and 41, the Mauvais-Jarvis et al. exemplifies a composition comprising a hydroalcoholic composition comprising the 4-hydroxytamoxifen, an aqueous vehicle (water), an alcoholic vehicle (ethyl alcohol), and a gelling agent (Carbopol 934) (see column 3, lines 30-40, in particular), whereas Parab. teaches providing the penetration enhancer, as discussed above. Accordingly, the combined teachings Mauvais-Jarvis et al. and Parab render the claimed composition obvious.

Regarding claims 31 and 39, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water, and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance

provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Regarding the amount of the isopropyl myristate provided, as recited in part (e) of claims 31 and 39, as well as claims 33 and 44, it is noted that Parab teaches that isopropyl myristate (IPM) can be incorporated in an amount of from 1 wt% to abut 30 wt% (see page 4, lines 35-45, in particular). Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 32 and 43, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular). Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition,

according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 34 and 45, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding claims 36 and 47, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 35 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over either (i) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990,

in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 26-28, 31-34, 36, 39-45 and 47 above, or (ii) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992, as applied to claims 31-34, 36, 39, 43-45 and 47 above, and further in view of U.S. Patent No. 5,720,963 to Walter P. Smith, issued February 24, 1998.

Mauvais-Jarvis et al. and Gunther et al or Parab, are applied as discussed for claims 31-34, 36, 39, 43-45 and 47 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising an active agent that "consists" or "consists essentially" of 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. also exemplify a composition comprising an aqueous vehicle in an amount that is close to and/or overlaps with that recited in claims 35 and 46. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the aqueous vehicle provided in the composition, according to the guidance provided by Mauvais et al. and Gunther et al or Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The references do not specifically teach providing an aqueous vehicle that is a phosphate buffered solution, as recited in claims 35 and 46.

Smith teaches topically applied treatments for skin, which can comprise gels (see abstract, in particular). Smith teaches that topical treatments can be pH adjusted to within a desired range and may be buffered with buffers such as trimethylolaminomethan (tromethane) or phosphate buffer (see column 32, lines 20-30, in particular), as recited in claims 35 and 46.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the buffers of Smith in the hydroalcoholic gel of Mauvais-Jarvis et al. and Gunther et al or Mauvais-Jarvis et al. and Parab, because Mauvais-Jarvis and Gunther et al. or Mauvais-Jarvis et al. and Parab teach the composition is applied percutaneously (topically), and Smith teaches the buffers can be provided to maintain a desired pH of the a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the buffers of Smith in the composition of Mauvais-Jarvis et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab, with the expectation of maintaining suitable pH of the composition for topical application.

Claims 38 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either (i) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990,

in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 31-34, 36, 39, 43-45 and 47 above, or (ii) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992, as applied to claims 31-34, 36, 39, 43-45 and 47 above, and further in view of further in view of U.S. Patent No. 6,013,270 to Hargraves et al, issued January 11, 2000.

Mauvais-Jarvis et al. and Gunther et al. or Parab, are applied as discussed for claims 31-34, 36, 39, 43-45 and 47 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising and active agent that "consists" or "consists essentially" of 4-hydroxy tamoxifen.

The references do not specifically teach that the composition is packaged in a unit dose packet of a multiple dose container with a metered pump, as recited in claim 38.

Hargraves et al. teaches a skin care kit having a skin care composition contained within a dispenser (see abstract, in particular). Hargraves et al. teaches that the dispenser can comprise a metered pump that provides multiple doses and is suitable for dispensing skin care compositions such as for medical applications and body care applications (see column 14, line 45 through column 20, line 15, in particular).

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the dispenser of Hargraves et al. to dispense the composition of Mauvais-Jarvis et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab, because Mauvais et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab teach a medical composition for percutaneous application (topical application), and Hargraves et al. teaches the dispenser dispenses topical compositions, such as medical compositions. Thus, one of ordinary skill in the art would have been motivated to provide the dispenser for the composition of Mauvais-et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab, with the expectation of providing a device suitable for the dispensing of the topical composition.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor